DRAFT AGENDA

ORTHOPEDIC AND REHABILITATION DEVICES PANEL of the

MEDICAL DEVICES ADVISORY COMMITTEE

Holiday Inn
Walker and Whetstone Ballrooms
2 Montgomery Village Avenue
Gaithersburg, Maryland
December 11, 2003

Panel Chairperson

Executive Secretary

Michael J. Yaszemski, M.D., Ph.D.

Janet L. Scudiero, M.S., acting

9:00 am Call to Order

Conflict of Interest and Deputization to Voting Member Status Statements

Panel Introductions

Update Since the January Date, 2001 Meeting

Barbara C. Zimmerman, Chief, Orthopedics Devices Branch

Reclassification of the Intervertebral Body Fusion Device (Cage)

9:15 am FDA Presentation

Jodi H. Anderson, MS, Orthopedics Devices Branch

10:00 am Industry Presentations

11:30 am Break

11:45 am Open Public Hearing, up to 60 minutes

12:45 pm Lunch

1:45 am Panel Deliberation

3:45 pm Break

4:00 pm Panel Deliberation continued,

Reclassification Questionnaire and Supplemental Data Sheet, and Vote

6:00 pm Adjournment

Notes

^{1.} During the open public hearing, interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, Dr. Yaszemski may ask them to remain if the panel whishes to question them. Then Dr. Yaszemski will recognize unscheduled speakers as time allows.

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